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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,286	12/13/2001	David Flyer	26747-34	2366

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,286	FLYER ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8, 14 and 24-30, drawn to a polypeptide immunogen and compositions thereof , classified in Class 530, subclasses 327, 328 and 350 and Class 424, subclasses 185.1., 193.1 and 197.11.

II. Claims 9-13, drawn to nucleic acids, vectors and recombinant cells, classified in Class 536, subclass 23.5 and Class 435, subclasses 252.3 and 320.1.

III. Claim 15, drawn to an antibody, classified in Class 530, subclass 387.1.

IV. Claims 16 and 17, drawn to a method for inducing a CTL response in vitro, comprising contacting a CTLp with a polypeptide immunogen, classified in Class 435, subclass 377.

V. Claim 23, drawn to a method for inducing an CTL response in vivo in an HLA-A2 positive subject comprising administering a polypeptide immunogen, classified in Class 424, subclass 190.1.

VI. Claims 18 and 20, drawn to a method for inducing a CTL response in vitro, comprising contacting a CTLp with a recombinant cell comprising a polynucleotide encoding a polypeptide immunogen, classified in Class 435, subclass 252.3.

VII. Claims 19, 21 and 22 drawn to a method for treating a subject with TB comprising adoptive transfer of CTLs, classified in Class 424, subclass 93.71.

VIII. Claims 31 and 32, drawn to a method for treating or protecting an HLA-A2 positive patient against TB, comprising administering an antibody, classified in Class 424, subclass 130.1.

2. Inventions I, II and III are different products.

Polypeptides, nucleic acids/vectors and recombinant cells thereof, and antibodies are distinct because their structures and modes of action are different, which require non-coextensive searches

3. Inventions IV-VIII are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of inducing a CTL response or treating a subject with TB. For example, the method of Invention IV comprises inducing a CTL response in vitro by contacting CTLp in vitro with a polypeptide immunogen, whereas the method of Invention V comprises inducing a CTL response in vivo in an HLA-A2 positive subject by administering a polypeptide

immunogen to the said subject, whereas the method of Invention VI comprises inducing a CTL response in vitro by contacting a CTLp with a recombinant cell comprising a polynucleotide encoding a polypeptide immunogen, whereas the method of Invention VII is one of adoptive transfer of CTLs to a TB positive subject, whereas the method of Invention VIII is a method for treating or protecting an HLA-A2 positive patient with/against TB comprising administering an antibody.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

6. Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

7. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

Therefore, they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VIII is not required for any other group from Groups I-VIII and Groups I-VIII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species of polypeptide immunogen/composition thereof (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted***, for example, SEQ ID NO: 1 or SEQ ID NO: 1wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

11. **If Applicant elects the Invention of Group II**, Applicant is further required to (1) elect a single disclosed species of polypeptide immunogen that is encoded by the polynucleotide and a specific species of polynucleotide/vector and recombinant cell thereof (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted***, for example, DNA encoding SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

12. **If Applicant elects the Invention of Group III**, Applicant is further required to (1) elect a single disclosed species of antibody specific for a specific polypeptide immunogen (an antibody ***specific for a specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted***, for example, an antibody specific for SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

13. **If Applicant elects the Invention of Group IV**, Applicant is further required to (1) elect a single disclosed species of polypeptide immunogen to be used in the claimed method (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted***, for example, SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

14. **If Applicant elects the Invention of Group V**, Applicant is further required to (1) elect a single disclosed species of polypeptide immunogen to be used in the claimed method (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted*** , for example, SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

15. **If Applicant elects the Invention of Group VI**, Applicant is further required to (1) elect a single disclosed species of mammalian cell comprising a vector comprising a specific polynucleotide encoding a polypeptide immunogen to be used in the claimed method (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted*** , for example, SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

16. **If Applicant elects the Invention of Group VII**, Applicant is further required to (1) elect a single disclosed species of CTLs specific for a specific polypeptide immunogen to be used in the claimed method (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted*** , for example, SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. **If Applicant elects the Invention of Group VIII**, Applicant is further required to (1) elect a single disclosed species of antibody specific for a specific polypeptide immunogen to be used in the claimed method (a ***specific SEQ ID NO or for a sequence differing from the specific SEQ ID NO by not more than 1 amino acid residue, a specific SEQ ID NO and the specific amino acid residue substituted*** , for example, SEQ ID NO: 1 or SEQ ID NO: 1 wherein the position 9 Val is substituted by another amino acid residue) to which claims would be restricted if no generic claim is finally

held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

18. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

22. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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